IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

EMED TECHNOLOGIES CORPORATION,	§	
	§	
PLAINTIFF,	§	
	§	**Civil Action No. 2:18-cv-00163-JRG-RSP**
V.	§	
	§	**JURY TRIAL DEMANDED**
ANDREW I. SEALFON AND REPRO-MED SYSTEMS, INC. (D/B/A RMS MEDICAL PRODUCTS),	§	
	§	
Defendant.	§	

PLAINTIFF'S FIRST AMENDED COMPLAINT

Pursuant to Rule 15(a)(1) of the Federal Rules of Civil Procedure,[1] EMED Technologies Corporation ("EMED" or "Plaintiff") hereby files this First Amended Complaint for antitrust, business disparagement and related violations against Andrew I. Sealfon ("Sealfon") and Repro-Med Systems, Inc. ("RMS") (collectively referred to as "Defendants"), showing this Court as follows:

I. INTRODUCTION AND BACKGROUND

1. EMED was founded in July 1991, and since its inception EMED has developed a cutting edge medical technology that improves the livelihood and quality of health care for patients while optimizing efficiency. EMED has worked with clinicians, inventors, and medical companies to develop innovative medical products for over two decades and has become the leader in design and manufacture of those products. EMED specializes in serving the following markets: home infusion, home healthcare, pharmacies, hospice, and hospitals, among others.

[1] The Original Complaint was served on or about April 26, 2018, therefore this First Amended Complaint is filed within 21 days of service.

2. EMED's products target various areas, including (1) intravenous therapy (infusion of a fluid directly into a vein), (2) implanted port therapy (infusion of a fluid into the body through an implanted device), and (3) subcutaneous therapy (infusion of fluid under the skin and not directly into a vein or through an implanted port).

3. EMED's complaint relates to subcutaneous therapy ("SC"); in particular EMED's leading products and inventions in the SC field, as they are being interfered with by anticompetitive behavior. More specifically, EMED's claims involved anticompetitive acts in the Subcutaneous Immunoglobulin ("SCIg") therapy for the treatment of Primary Immunodeficiency Diseases ("PIDD") space. Recently referred to as Primary Immunodeficiency or PI, it is a genetic condition in which a person's immune system does not naturally generate sufficient immunoglobulin ("Ig"), i.e., antibodies that play a critical role in human immunity and protection against infection. PI may be treated by the infusion of immunoglobulin needed for the immune system to fight off infections. Therapy by the subcutaneous infusion of immunoglobulin has advantages over traditional intravenous therapy for many patients, allowing them to minimize hospital time and to regularly handle their therapy in the comfort of their own homes.

4. EMED's claims relate to the needle sets, rate control sets (or Infusets), and pumps used in connection with subcutaneous therapy, including SCIg therapy. While these devices may be used for other SC therapies, the focus is on SCIg therapy.

5. SCIg needle sets generally comprise a needle portion for penetration of patients' skin and tubing through which the fluid is delivered and that connects to other parts of the infusion device ("SCIg Needle Sets" or "SCIg Safety Needle Sets"). The needles, generally less than one inch long, come in different gauges, with higher gauge needles (e.g., 27) having a smaller diameter than lower gauge needles (e.g., 24). The tubing can have various lengths of up to 40 inches or

more. The "flow rate" of fluids through SCIg Needle Sets is impacted by various factors, including, for example, the length of the tubing and the gauge of the needle. Due to the viscosity of Ig and the necessary flow rates, multiple needles may be required during one therapy session.

6. The fluids are generally introduced through the SCIg Needle Sets using a pump that pumps the fluid at a controlled rate ("Infusion Pumps"). Accompanying Rate Control Sets are required when mechanical pumps are selected to administer SCIg therapy and they are connected between the pump and the needle sets.

7. EMED is and was a pioneer in the development of SCIg and other infusion therapy devices. EMED pioneered the development of needle sets specifically optimized for infusion of immunoglobulin to patients with PI in 2005. Initially, EMED was the only manufacturer and supplier of SCIg-optimized-Needle Sets.

8. EMED also focused on safety in connection with SC therapy, and has invented various ways to protect patients and medical practitioners from inadvertent needle sticks. Needle safety features are increasingly important in the marketplace to both limit clinician exposure as well as help immune-compromised patients avoid needle-stick injuries. In the United States, the Needlestick Safety Prevention Act was signed in 2000 and made effective in 2001. This act required that regulators clarify safety regulations pertaining to needles and other "sharps," resulting in regulations specifying that needles should include safety features.

9. EMED, around 2007-2008, began incorporating additional innovative design features into its SCIg needle sets ("SCIg Needle Sets"), which it began selling in or around July, 2008. EMED's SCIg Needle Sets became the standard against which later-introduced SCIg Needle Sets were measured.

10. In 1994, EMED obtained FDA clearance for a family of extension Sets for the infusion of fluids with any infusion apparatus and application, including any SCIg Needle Sets and Infusion Pumps and has produced hundreds of thousands of Rate Control Sets for various applications since.

11. In addition to its pioneering the SCIg Needle Sets, EMED developed a novel variable rate control set, VersaRate, to optimize Ig administration with mechanical pumps. This clinically important device improves SCIg therapy allowing patients to make adjustments when environmental conditions and/or variations in and across patients change infusion rates undesirably, an inherent limitation to mechanical pumps. VersaRate provides significant clinical benefits to patients. For example, in Canada, it has been shown that pediatric patients can benefit from using EMED's VersaRate set to simplify therapy by allowing them to reduce the rate during the first infusion allowing children to become familiar with the setup. The VersaRate obtained FDA market clearance in or around December of 2012 and is currently patent pending with a priority date of November 30, 2011.

12. EMED also developed the "SCIg60" Infusion Pump, which is an improved version of an infusion pump distributed and used in the market for the last 20 years, which is also still being used and distributed in the market today. EMED received clearance for its SCIg60 Infusion System on or about May 14, 2015 under 510k K142319. EMED's SCIg Infusion System was the first pump to obtain FDA clearance for SCIg therapy.

13. Given the nature of mechanical pumps, especially when used for administration of viscous fluids such as Ig, empirical calculations are required to characterize the flow rate of an Infusion Pump in conjunction with Rate Control Sets and Safety Needle Sets. A "Calculator" refers to the summary of these empirical flow rate calculations. The Calculator provides clinicians

and pharmacists the ability to determine specific Rate Control Sets and Needle sets that should be used to attain a desired therapy concentration for a specific patient. The information in the Calculator ensures that a patient be prescribed with the proper Ig therapy.

II. MARKET DEFINITIONS

14. Plaintiff EMED on behalf of itself, based on information and belief, and investigation of counsel, except for information pertaining to the Plaintiff, which is based on their personal knowledge, alleges as follows:

15. RMS, Inc. ("RMS" or "Defendant") owns and operates a manufacturing operation for commercializing infusion systems, in the subject SCIg therapy market, allegedly covered by the scope of the claims of the RMS Published Patent Applications (2015/0374911 ("the '911 Publication" titled Multi-Flow Universal Tubing Set) and 2016/0256625 ("the '625 Publication" titled Precision Variable Flow Rate Infusion System and Method)). RMS's website can be found at http://www.rmsmedicalproducts.com/. The '625 Publication is likely to issue as a patent shortly given that its counterpart and exactly corresponding Canadian application issued as Canadian Patent 2,977,099. On various occasions RMS and Sealfon have stated that their Infusion System is "the only patented system."

16. The SCIg market is a relatively small market serving approximately 18,000 patients in the United States. However, in 2005 approximately 250,000 patients were diagnosed with PI in the U.S. alone. The general trend is to enable patients with this condition to be self-treated at home, thereby increasing quality of life, improving therapeutic benefits of timely infusions and reducing cost.

17. Consumers and merchants recognize the SCIg market as a home based, subject self-administered immunoglobulin therapy. The "Subject Self-administered SCIg Therapy Market" is defined as the market for self-administered Subcutaneous Immunoglobulin ("SCIg") therapy for

the treatment of Primary Immunodeficiency Diseases ("PIDD" or "PI") that RMS alleges are within the scope of the claims of the RMS Published Patent Applications.

18. To administer immunoglobulin fluids subcutaneously, as a home therapy, special devices are required generally including: an infusion pump and subcutaneous needle sets. Accordingly, the relevant product markets include self-administered infusion systems for the subcutaneous delivery of immunoglobulin ("Product Market").

19. The immunoglobulin fluids are generally introduced through SCIg Needle Sets using a pump that pumps the fluid at a controlled rate ("Infusion Pumps"). Accompanying extension sets, or Rate Control Sets, also may be used to connect the SCIg Needle Sets to the Infusion Pumps. Mechanical Infusion Pumps can normally last 10-15 years apiece, while Rate Control Sets and SCIg Needle Sets are single use devices and represent the more significant and recurring sales in this market.

20. RMS has market power in the Subject Self-administered SCIg Therapy Market taking into consideration RMS's illegal marketing strategy, the RMS Product Disparagement of EMED's competing infusion systems, the Sealfon Product Disparagement of EMED's competing infusion systems, the RMS Published Patent Applications, Sealfon's actions,[2] and RMS's products; RMS has, on information and belief, an approximate 65-70% market share of the Subject Self-administered SCIg Therapy Market. However, RMS's illegal marketing strategy, including the RMS Product and Business Disparagement of EMED competing infusion systems, the Sealfon Product Disparagement of EMED competing infusion systems, and both

[2] Sealfon's actions include1)disparagement of EMED and its devices; 2) Misrepresentation of performance of EMED devices; 3) Misrepresentation of the compatibility of EMED devices with RMS devices; 4) Copying of EMED devices; 5) Promotion of RMS devices in the SCIG market before market clearance; 6) Removal of EMED needle sets from the RMS calculator; 7) Misrepresentation of the characterization of RMS devices; (8) Transmission of false reports to FDA in an attempt to remove EMED's devices from the marketplace; (9) Misrepresenting EMED's product's regulatory status to the pharmacies and clinicians; 10) Attempting to patent devices copied from EMED and, 11) the others.

the patent position of RMS and attempted patent position of RMS[3] are primary reasons for RMS's market position and power. Further, RMS's marketing techniques are such that consumers in the industry assume RMS has market power.

21. Consumers and merchants have come to recognize the Subject Self-administered SCIg Therapy Market as a separate and distinct market from the PI Therapy Market. The PI Therapy Market includes patients with disorders caused by an inherited flaw in the immune system that increases the susceptibility to infection.

22. Barriers to entry into the Subject Self-administered SCIg Therapy Market are high. In addition, the barriers to entry into the Subject Self-administered SCIg Therapy Market imposed by RMS's illegal marketing strategy, include the RMS Product Disparagement of EMED competing infusion systems, the Sealfon Product Disparagement of EMED competing infusion systems, Sealfon's illegal anticompetitive behavior, discussed in detail herein. Other barriers to entry include the fact that: (1) the development of intellectual property around any new product takes many years; (2) any new product takes time to gain FDA clearance; and, (3) any new entrant would have to offer an inventory of needle sets, infusion tubing, rate sets, and/or pumps, necessitating, an inordinate investment of capital and resources.

23. The Subject Self-administered SCIg Therapy Market offers a number of features not readily available with other infusion systems, including, but not limited to:

a. personalized ad-hoc therapy without nursing or hospital time;

b. improved levels of Ig through the with a consequential improved immune system and reduced health issues;

c. ease of use;

[3] Notwithstanding EMED's belief that RMS copies EMED products and then seeks to patent them.

d. special needle set configurations;

e. low cost mechanical pump;

f. adjustable rates of infusion;

g. protection from accidental needle stick; and,

h. the like.

24. The relevant geographic market for the Subject Self-administered SCIg Therapy Market is world-wide, including the United States and its Territories. Further, Sealfon's and RMS's disparagement of EMED and its products is worldwide.

25. RMS and Sealfon have and are engaged in tying and monopolizing behavior, placing unneeded and unjustifiable restrictions on product selection for its infusion system products in an effort to restrict consumer choice and restrain competition in the Products Market and Subject Self-administered SCIg Therapy Market, i.e. for example previously asserting the use of EMED products might harm patients and presently asserting that the use of EMED products with RMS products cannot be guaranteed and/or may void warranties.

26. As alleged in further detail below, RMS and Sealfon deliberately prohibit competition with the RMS infusion system products, in the Subject Self-administered SCIg Therapy Market, through anticompetitive marketing terms and contract terms that stifle innovation and interfere with commerce to such an extent that RMS can and does sell its Infusion system products and accessories at prices far above those that would prevail in a competitive market for Infusion systems and its accessories and products in the Subject Self-administered SCIg Therapy Market.

III. JURISDICTION AND VENUE

27. Jurisdiction is conferred upon this judicial district pursuant to at least 15 U.S.C. §§15 and 28 U.S.C. §§1331 and 1367.

28. RMS is subject to personal jurisdiction in this judicial district because RMS has purposefully availed itself of the privilege of doing business in this judicial district and has sufficient minimum contacts with Texas to render the exercise of jurisdiction over RMS compatible with due process. RMS maintains distributors, including Right Way Medical, LLC; Owens & Minor; and, others, in this judicial district and transacts business in Texas, including targeting sales and marketing of its products in this judicial district through such distributors and others including Medical Specialties Distributors in Dallas, Coram CVS Specialty Infusion Services in Austin, Bioscript Solutions in Austin, and various Walgreens locations in Dallas and this Judicial District. Further, the RMS actions complained herein targeted consumers in the State of Texas and this judicial district. Further, Plaintiff's cause of action arises directly from RMS's business contacts and other activities in the State of Texas and in this judicial district.

29. Sealfon is subject to personal jurisdiction in this judicial district because Sealfon has purposefully availed himself of the privilege of doing business in this judicial district and has sufficient minimum contacts with Texas to render the exercise of jurisdiction over Sealfon compatible with due process. Further, the Sealfon actions complained herein targeted consumers, including customers of EMED, in the State of Texas and this judicial district. Further, Plaintiff's cause of action arises directly from Sealfon's business contacts and other activities in the State of Texas and in this judicial district.

30. Venue is proper in this district pursuant to at least 15 U.S.C. §§15 and 22; and, 28 U.S.C. §§1391(b) because Defendant RMS transact business in this district through direct sales and has distributors in this district. Further, the acts complained of have had, and will have, substantial anticompetitive effects in this district.

IV. TRADE AND COMMERCE

31. During all relevant time periods, RMS and Sealfon marketed, distributed, and sold its Infusion systems, including its pumps, it's needles sets, Rate Control Sets and other accessories, with the anticompetitive terms in a continuous and uninterrupted flow of intrastate and interstate commerce throughout the United States and throughout the world.

32. During all relevant time periods, RMS and Sealfon disparaged EMED and its products to EMED's customers throughout the U.S., including the State of Texas and this judicial district, and throughout the world.

V. RMS ENGAGES IN ILLEGAL TYING CONDUCT THROUGH ITS PRODUCT USE RESTRICTIONS

33. For the purposes of this Complaint, the tied product is the RMS HIgH Flo subcutaneous Needle Sets and, in various combinations, the RMS Rate Control Sets, and the tying product is RMS's Infusion System (Freedom60 and Freedom Edge). Thus, consumers who have purchased Infusion System (Freedom60 and Freedom Edge) from RMS will have no choice but to buy HIgH Flo subcutaneous Needle Sets and, in various combinations, RMS Rate Control Sets, from RMS. Sealfon and RMS further compound the anticompetitive behavior by alleging EMED products will not work to standard with RMS products by such false statements as, but not limited to:

a. The FDA indicates the Infusion System (Freedom60 and Freedom Edge) must be used only as a system with other RMS components;

b. The Infusion System (Freedom60 and Freedom Edge) components will not work and can harm people when components other than RMS components are use; and,

c. The warranty for the Infusion System (Freedom60 and Freedom Edge) only applies if use with other RMS components.

34. Sealfon and RMS make these false statements in spite of the fact that the FDA cleared EMED's rate set as "Substantially Equivalent" per EMED's rate set 510k and other 510k's.

35. RMS has for some time sold an Infusion Pump and Rate Control Sets. Ironically, RMS's Freedom 60 pump, which became prominently used for Immunoglobulin, was intentionally marketed for such application without FDA clearance for many years before obtaining market clearance in August of 2017. The unauthorized marketing occurred even after a Warning Letter was issued by the FDA noting RMS's unauthorized marketing of its Freedom 60 pump. Such illegal marketing resulted in RMS gaining an undue but dominant position in the United States, where mechanical pumps are currently the only pumps for which consumers can receive reimbursement in this market segment.

36. RMS is a major player in the market for both Infusion Pumps and Rate Control Sets because it has engaged in a pattern of false advertising and business and product disparagement designed to interfere with EMED's sales relationships and to steer EMED's customers away from EMED's SCIg Needle Sets, pumps, and rate sets and towards RMS's alleged HIgH-Flo needle sets, rate sets and pumps. RMS's strategy for marketing its SCIg Needle Sets, rate sets and pumps has been to mislead the relevant purchasing public about the quality of its products and to disparage EMED's goods so RMS could wrongfully divert business away from EMED.

37. At the same time, RMS has engaged in a pattern of misrepresentations and product disparagement designed to pervert the market for Infusion Rate Control Sets, needles sets and pumps and thereby preclude EMED from competing fairly in those markets. RMS has widely

disseminated false and disparaging comments about EMED and EMED's products in an effort to prevent EMED from entering the market.

38. RMS's wrongful conduct has caused significant economic and reputational injury to EMED. RMS's approach appears to be to maintain its dominant market shares in the Infusion Pump market and the Rate Control Set portion of the Subject Self-administered SCIg Therapy Market, by falsely claiming that EMED's comparative offerings are unsafe or cannot be used with RMS's Infusion Pumps. RMS seeks to divert business away from EMED in the Subject Self-administered SCIg Market.

A. RMS's Misrepresentations and Product Disparagement Targeted at EMED'S Safety Needle Sets.

39. EMED was the first to introduce SCIg Needle Sets into the market in July 2005 and has since been a leader in that market. RMS did not start selling SCIg Needle Sets until sometime after May 2011. RMS promotes its SCIg Needle Sets through false advertisement as well as through dissemination of disparaging comments about EMED's comparative offerings. As a result of this false advertising and disparagement campaign, RMS has wrongfully diverted sales of SCIg Needle Sets and other products away from EMED in the Subject Self-administered SCIg Market.

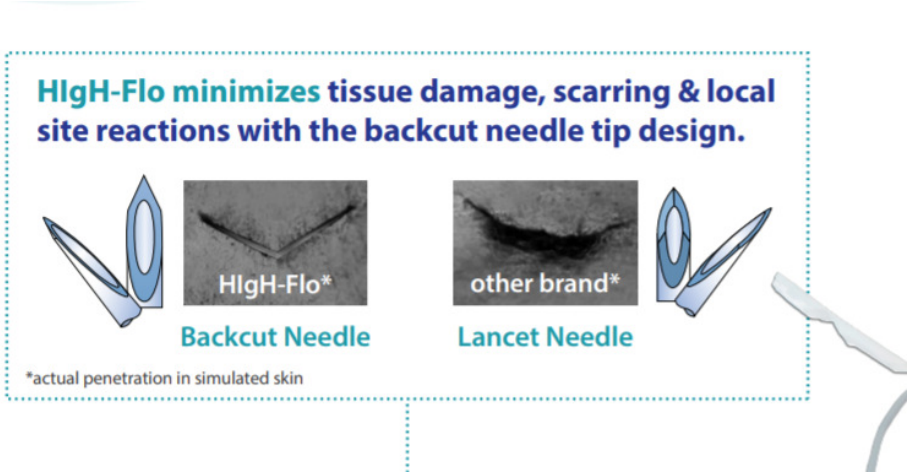
40. On information and belief, RMS knew that EMED Safety Needle Sets represented a significantly larger portion of the Subject Self-administered SCIg Market than that of the pump and Rate Control Sets, and thus copied EMED's Safety Needle Sets including EMED's needle safety patent. RMS labeled the RMS sets "HIgH-Flo," apparently to insinuate that such HIgH-Flo Safety Needle Sets[4] had better flow characteristics than the EMED SCIg Needle Sets. However, empirical data, and the FDA clearances obtained by EMED, establish EMED device flow rates and RMS device flow rates are substantially the same with no consequential difference.

[4] RMS has developed at least three generations of HIgH-Flo needles sets.

41. RMS also removed EMED Safety Needle Sets from its Calculator—a move which prevents pharmacists and nurses in the Subject Self-administered SCIg Market from using EMED Safety Needle Sets and consequently promotes the RMS products, including the RMS infusion pumps, Rate Control Sets and needle sets.

1. Sealfon and RMS Falsely Claim That Its SCIg Needle Sets Reduce Infusion Site Reactions.

42. Pain, swelling, and redness are known and common site reactions resulting from SCIg administration because of the Immunoglobulin itself. Using the same site for infusions can help reduce the amount of local swelling or redness that can occur after an infusion. On information and belief, the following imagery used by Sealfon and RMS is not from RMS clinical testing but unrelated random imagery.



43. RMS used these and other false and misleading representations regarding injection site reactions, as a springboard to introduce and market its so-called "HIgH-Flo" SCIg Needle Sets. RMS's representations and false data confused the relevant purchasing public about the characteristics of RMS's and EMED's SCIg Needle Sets and misled customers into believing that RMS's HIgH FloSCIg Needle Sets minimize adverse site reactions and EMED's comparative offerings were responsible for causing adverse reactions. As a designer and manufacturer of SCIg Needle Sets, RMS knew or should have known that its data was misleading because it knew or should have known the causes of the alleged difference in site reactions between its SCIg Needle Sets and EMED's Safety Needle Sets.

44. RMS's false advertisement promoting its SCIg Needle Sets as better devices and its widely publicized disparaging statements about EMED's SCIg Needle Sets have cast doubt in the SCIg market about the quality of EMED's products and have further interfered with or disrupted the economic relationships between EMED and its existing and/or potential customers. EMED has suffered actual injury in the form of lost sales of its Needle Sets, Rate Control Sets and pumps as a direct and proximate result of RMS's conduct.

45. Because EMED is a leading provider for SCIg Needle Sets and is RMS's primary competitor in that segment of the SCIg market, buyers and potential buyers understand that the "other brand" referred to in RMS's publications, which uses a lancet type needle, refers to EMED. EMED customers, including at least the Kroger Company, Accredo Specialty Pharmacy and others, have contacted EMED worried about RMS's false representations concerning EMED's needle tips.

46. Further, the foregoing RMS publications published on RMS' website and/or disseminated to influential market consumers including but not limited to Coram, Accredo Specialty Pharmacy, BioRx, and BioScrip, presented no data to support its representations about the actual penetration forces applied in use of the needle sets or no clinical data relative to the outcome when using these devices comparatively. As a designer and manufacturer of SCIg Needle Sets, RMS knew or should have known that the generally accepted methodology for testing sharpness and/or penetration was through controlled studies using a test membrane and that the studies presented in its publications were unreliable. Nevertheless, RMS published this unsubstantiated disparaging information with reckless disregard for the truth of its content and with the intent to steer customers away from EMED and to RMS when RMS does not have FDA clearance to make such claims.

2. RMS Falsely Claims EMED's SCIg Needle Sets Are Dull and Damage Patients' Skin.

47. RMS also initiated another disparagement campaign against EMED's Safety Needle Sets by alleging that EMED's sets were dull and caused coring. Coring is a term which describes the shearing-off of a portion of the material a needle must penetrate to perform its function; for SCIg administration, coring refers to the shearing off or damaging of patients' skin.

48. For example, during an online training, RMS' National Manager, stated that RMS's needles are non-coring and that the competitor's Safety Needle Sets core. The reference to competitor was clearly meant to refer to EMED, as the participants in the market would understand. This appears to be RMS's script at ongoing training sessions, both on-line and trade shows. However, the script is patently false.

49. EMED's Safety Needle Sets have been independently tested for sharpness and penetration using a skin-like test membrane. This test membrane methodology is the generally accepted method for testing penetration force and thus a measure of needle sharpness. EMED's studies confirmed that EMED's needles were not dull, and, when compared to RMS's needle set, actually required far less force than RMS's needles to penetrate the test membrane.

50. Although RMS purports to the market that its HIgH-Flo Safety Needle Sets are an important RMS design, it comes from B Braun's design which was made for other therapies and not intended for subcutaneous use. On information and belief, RMS has not conducted a clinical trial regarding either RMS' HIgH-Flo Safety Needle Sets or EMED's SCIg60 Safety Needle Sets. The images RMS and Sealfon used in its advertisements against EMED, illustrated above, are not pictures of the actual use of either RMS' or EMED's Safety Needle Sets, nor are they documented in the FDA database of clinical trials.

51. RMS's and Sealfon's false and disparaging comments about EMED's products have significantly interfered with and disrupted the economic relationships between EMED and its existing and potential customers, hindered EMED's efforts to market its own products, and wrongfully diverted business away from EMED.

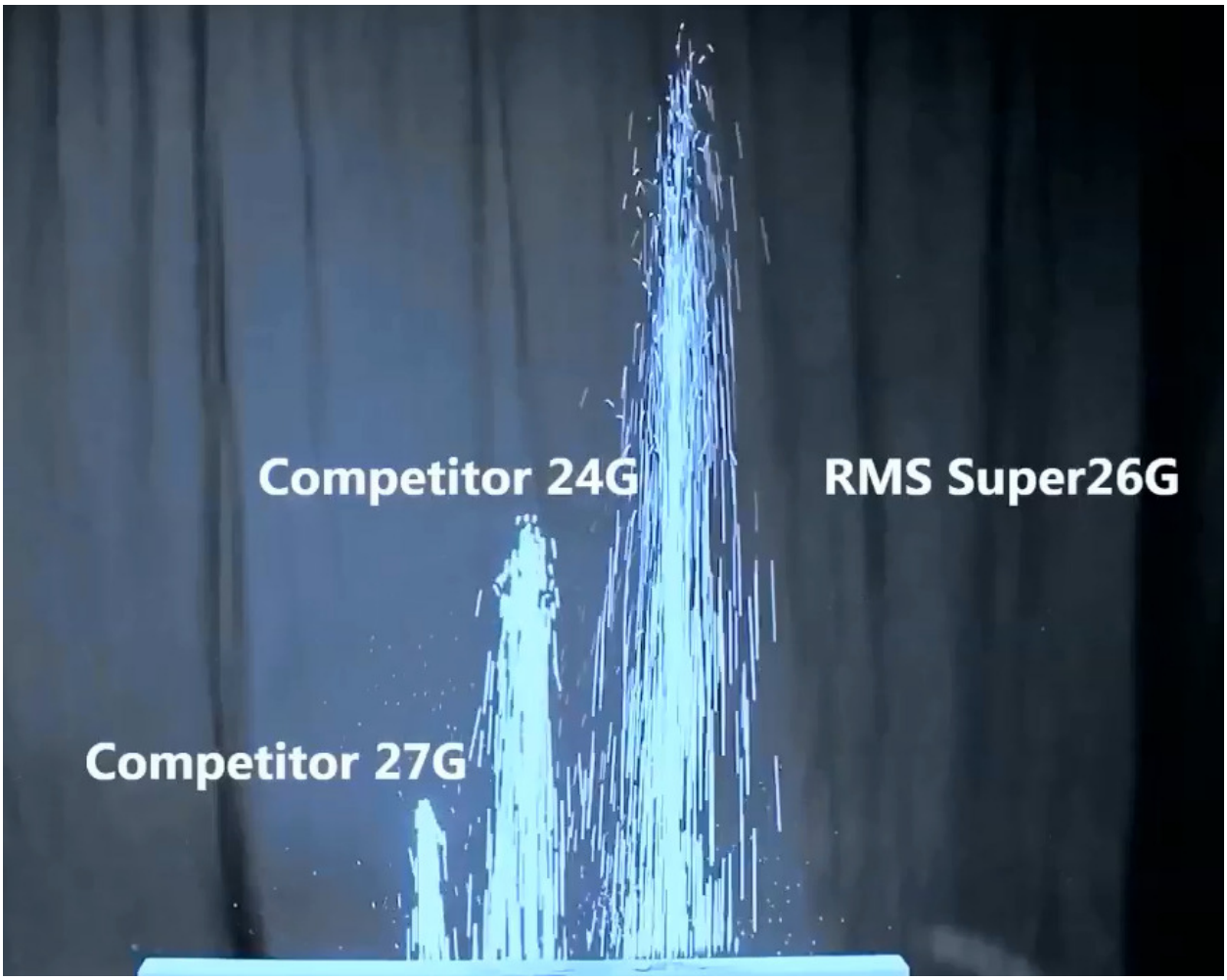
52. RMS and Sealfon have made, and continues to make the same or similar false allegations regarding the sharpness of EMED's SCIg Needle Sets in its conversations with, or sales

representations to, customers in the market, including customers located in Texas, including one or more of:

1. VA Medical Center, Dallas, Johnny White -- Bonham, TX
2. All Home Infusion Inc. -- Flint, TX
3. CVS/Specialty #48604-CAREMARK LLC -- Flower Mound, TX
4. Frisco Allergy & Asthma Center -- Frisco, TX
5. US Bioservices TX -- Frisco, TX
6. Walgreens Specialty Pharmacy # 13625 -- Frisco, TX
7. Logic Medical -- Frisco, TX
8. US BIOSERVICES CORP – TX -- Frisco, TX
9. Americare Infusion Center -- Lewisville, TX
10. CSL Behring -- McKinney, TX
11. AirCare -- Plano, TX
12. Texas Star Pharmacy -- Plano, TX
13. CarePoint Partners – Texarkana -- Texarkana, TX
14. Artex Medical -- Texarkana, TX
15. NORTH HEIGHTS PHARMACY -- Wake Village, TX

RMS's and Sealfon's actions and statements have cast a shadow of doubt in the Subject Self-administered SCIg Therapy Market, including the market for the SCIg Needle Set, about the quality of EMED's products and have further interfered with or disrupted the economic relationships between EMED and its existing and potential customers. EMED and its products have suffered financial and reputational injury.

53. In April of 2018 directly ahead of NHIA, one of the largest infusion trade shows in the US, RMS posted a video on the Internet at https://www.youtube.com/watch?v=0cao1fghREI which disparages EMED and its needle sets by showing misleading and mischaracterized information about EMED and RMS needle sets. The video refers to EMED sets as "Competitor 24G and 27G" which have been procured by EMED's for SCIG applications and to RMS set as "RMS Super 26G".



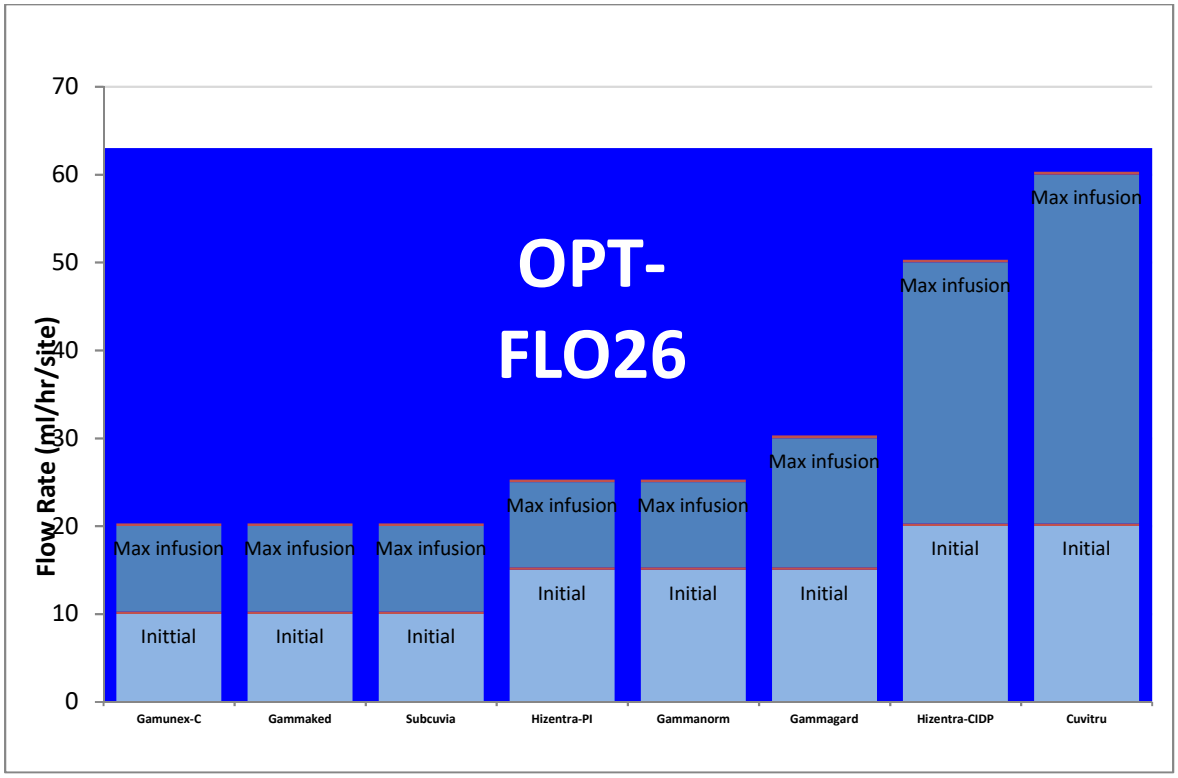
54. The above screen shot is taken from the video. Consistent with previous RMS marketing materials, this ad lacks technical data and is designed to confuse the market with references that are neither accurate nor validated. In this grotesque video jointly with other trade show materials, RMS misleads the market by presenting EMED sets without sufficient flow and RMS sets as able to attain faster flow rates.

55. The fact is that EMED started marketing its 26G OPT-FLOW SCIG sets during the third quarter of 2017, which addressed flow requirements of emerging biologics and their indications to be administered with SCIg therapies. During the NHIA show in April of 2018, RMS announced “coming soon” sets that are an evident attempt to copy EMED’s 26G OPT-FLO sets.

Without providing technical data, RMS is attempting to make believe its "Super" 26G are an innovation and better than EMED's sets. RMS deliberately omits the very EMED sets it copied as well as actual pertinent accurate technical information from the video and other materials.

56. EMED's OPT-FLO G26 sets satisfy all flow rates needed and even if RMS "Super 26G" sets were to have success in copying EMED OPT-FLO G26 sets, they would be limited to the monographs of what FDA clearances allow for each of the drugs as shown on the charts (i.e. Maximum levels). The chart below illustrates empirical test data for EMED OPT-FLO G26 sets for each of 8 biologics currently in the SCIg market with their corresponding flow rate indications.

EMED OPT-FLO 26G EMPIRICAL FLOW RATE DATA CHART



B. RMS's Misrepresentations and Product Disparagement Targeted at EMED's Rate Control Sets.

57. Rate Control Sets (also sometime known as rate sets) are necessary when mechanical pumps are used. Precisely manufactured tubing sets are designed to control the flow rate given a source of mechanical power. EMED is one of two suppliers of Rate Control Sets for use with the FREEDOM60. The other is RMS.

58. For more than 25 years, EMED has produced special tubing sets including Rate Control Sets for several corporations including industry leaders and small companies. From 2002 to 2005, RMS contracted with EMED for the manufacture of special microbore tubing, the key component of RMS' Rate Control Sets. During this time, EMED sold at least 155,000 units of microbore tubing to RMS. Although tubing specifications can be derived mathematically and empirically, RMS provided EMED with the necessary specifications to manufacture the RMS tubing, including tubing length, inner diameter, outer diameter, and the required flow rate to be achieved. EMED has had the know how to design and produce flow control sets for mechanical pumps including the Freedom60 and other mechanical pumps for decades. EMED's Extension set 510K clearance was originally obtained in 1994 covering a spectrum of configurations and flow rates. Notwithstanding the above, RMS began representing to customers that the EMED Extension sets lacked FDA clearance for the RMS Freedom60 pump and that EMED's sets could cause severe patient injury or death.

59. RMS has made multiple representations to customers that EMED's devices should not be used with the Freedom 60 pump. RMS published a "Safety Bulletin" which it circulated in multiple countries including US, Europe and Canada to falsely represent to customers that EMED's Rate Control Sets could cause severe patient injury or death and that they did not have FDA clearance.

60. However, the FDA cleared EMED's Rate Control Sets in 1994 for broad use with all infusion therapies. To obtain a pump-specific clearance, EMED submitted to the FDA the pertinent flow rate information it developed for EMED's Infusets when used with the Freedom60 pump after which the FDA issued a new 510k clearance. Despite the newly issued 510k clearance (K140133) issued on May 15, 2014 explicitly covering Infuset to be used with the Freedom60, RMS continues to falsely represent that EMED's devices are not cleared for RMS's Infusion Pump. Sealfon also changed the name of its Rate Control Sets to Precision and promoted a campaign stating that "only" Precision sets provide assurance and accurate rate with the Freedom60 pumps. RMS's representations concerning EMED's Infusets are false.

61. Further, to damage EMED's reputation and deter consumer purchases of EMED's Rate Control Sets, RMS unlawfully conditioned the validity of its pump's warranty on the use of RMS-branded accessories. Specifically, RMS publicly advertised that FREEDOM60 Pump users who use any non-RMS products with its pump voids the pump's warranty.

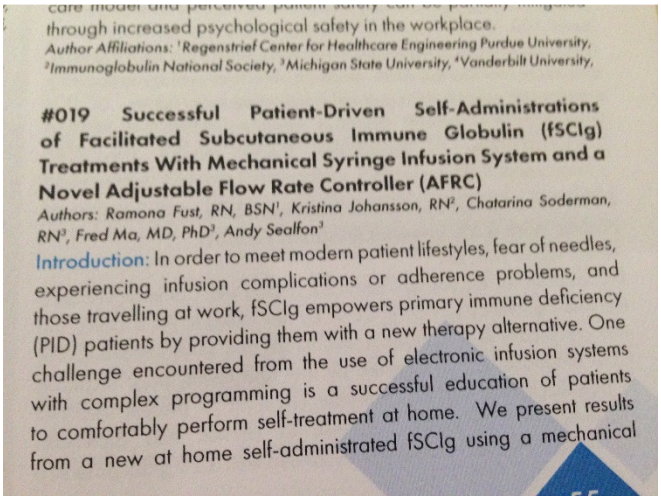
> Conditions of Warranty: This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its ability or reliability, or which has been subjected to misuse, negligence or accident. Misuse includes, but is not limited to, use without

compliance with the device operating instructions or use with non-approved accessories or disposable items.

62. The implicit and explicit messages were that EMED's Rate Control Sets were unsafe for use with RMS's pump. A consumer in the Subject Self-administered SCIg Therapy Market would understand the statement to mean that using EMED's Rate Control Sets would damage the pump and/or injure the patient. Such statements are of such shocking character that they are likely to cause immediate and irreparable harm to the Subject Self-administered SCIg Therapy Market and EMED.

63. The statements further reveal a concerted effort on the part of RMS to remove EMED from the Subject Self-administered SCIg Market by any means possible. The statements were meant to cause and likely did cause consumer confusion concerning whether EMED's products, devices, and accessories are cleared for use with RMS pumps and/or whether EMED's products, devices, and accessories are potentially life-threatening.

64. After initially stating that only fixed Rate Control Sets should be used with RMS pumps, Sealfon and RMS copied EMED's patent pending variable rate control set (VersaRate). RMS and Sealfon later published a technical poster containing the characteristics of EMED's SCIG variable flow rate invention and claiming ownership of it.



through increased psychological safety in the workplace.

Author Affiliations: [1]Regenstrief Center for Healthcare Engineering Purdue University, [2]Immunoglobulin National Society, [3]Michigan State University, [4]Vanderbilt University,

#019 Successful Patient-Driven Self-Administrations of Facilitated Subcutaneous Immune Globulin (fSCIg) Treatments With Mechanical Syringe Infusion System and a Novel Adjustable Flow Rate Controller (AFRC)

Authors: Ramona Fust, RN, BSN[1], Kristina Johansson, RN[2], Chatarina Soderman, RN[3], Fred Ma, MD, PhD[3], Andy Sealfon[3]

Introduction: In order to meet modern patient lifestyles, fear of needles, experiencing infusion complications or adherence problems, and those travelling at work, fSCIg empowers primary immune deficiency (PID) patients by providing them with a new therapy alternative. One challenge encountered from the use of electronic infusion systems with complex programming is a successful education of patients to comfortably perform self-treatment at home. We present results from a new at home self-administrated fSCIg using a mechanical

65. Neal Ross, an SCIg patient advocate, was told by Sealfon, "[i] will copy that too" referring to RMS's copying of VersaRate. Sealfon personally presented an RMS copied version of EMED's VersaRate at the RMS booth at the ESID in Prague in 2014.

66. Sealfon then took RMS's copied device to Baxter International, Inc., in an attempt to develop a "System" for Baxter's Ig (Hyquvia), specifically copying EMED's VersaRate and profiting from selling EMED's patent pending idea to Baxter. However, RMS was unable to deliver a working system within the terms of RMS agreement with Baxter.

67. During the Barcelona 2016 ESID Congress, Sealfon presented a poster that defined the benefits of RMS's copied version of Versarate.

68. Because of the substantial likelihood for irreparable harm resulting from RMS' statements regarding EMED's the United States District Court for the Eastern District of California issued a preliminary injunction against RMS on or about June 17, 2015, which enjoined RMS from advertising, publicly disseminating, or for a commercial advantage making statements including statements that:

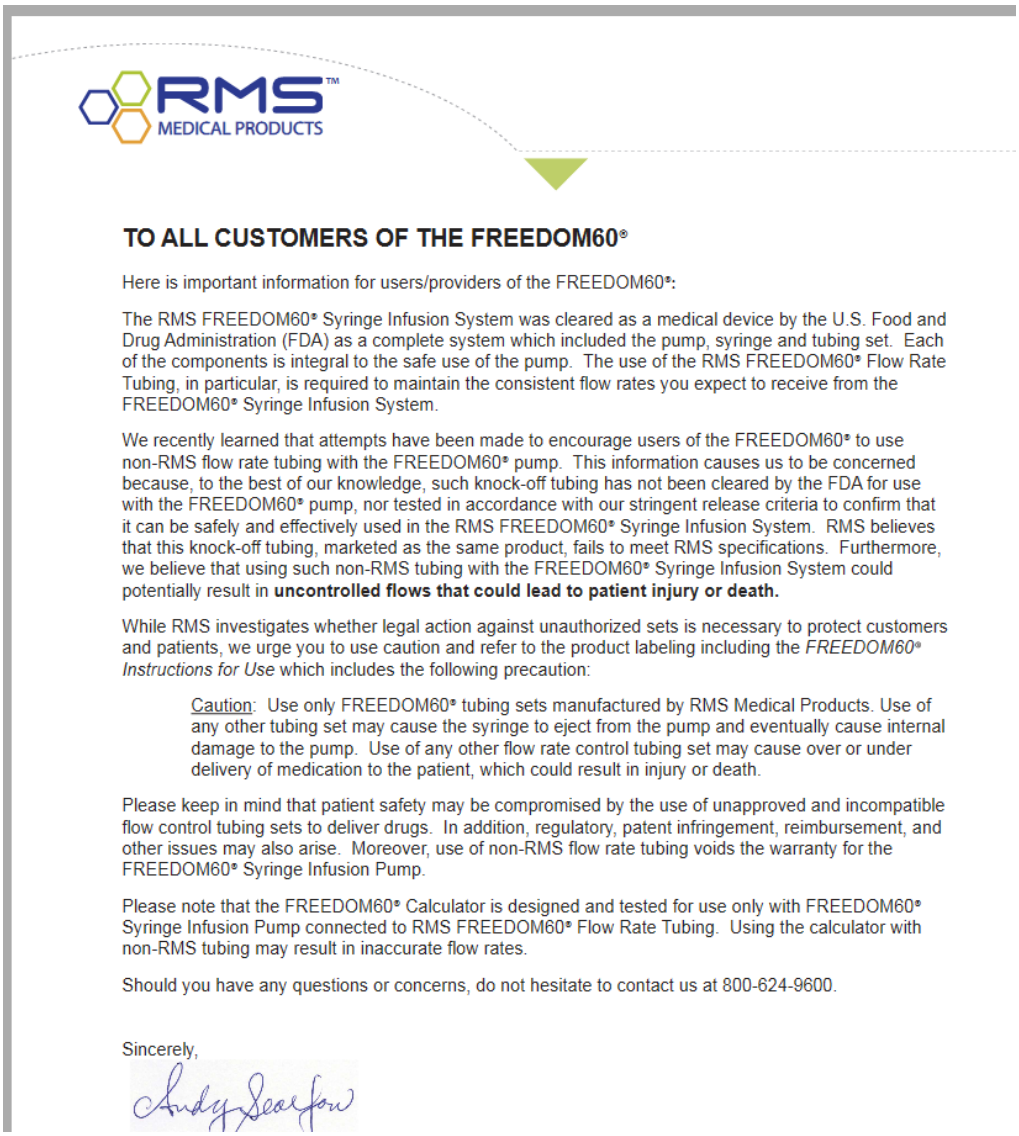
> (1) only RMS rate sets (flow rate control tubing sets) have FDA clearance for use with the Freedom 60; (2) only RMS rate sets (flow rate control tubing sets) may be safely used with the Freedom 60; (3) the warranty on the Freedom 60 is conditioned upon use of RMS rate sets (flow rate control tubing sets); or (4) are otherwise inconsistent with the 510(k)s issued by the FDA for the devices at issue in this case, including: the January, 1994 510(k) (No. K935642); the December, 2012 510(k) (No. K123729) for the VersaRate; and the May, 2014 510(k) (No. K140133) for Infusets.

69. Initially, RMS campaigned against EMED in a "Safety Bulletin," (below) published on RMS' website, distributed to its customers, and listed as the top google search entry when typing in "Freedom60 customers," in which RMS alleged that EMED's Infusets were unsafe for use with Freedom60:

> We recently learned that attempts have been made to encourage users of the FREEDOM60 to use non-RMS flow rate tubing with the FREEDOM60 pump.

> This information causes us to be concerned because, to the best of our knowledge, such knock-off tubing has not been cleared by the FDA for use with the FREEDOM60 pump, nor tested in accordance with our stringent release criteria to confirm that it can be safely and effectively used in the RMS FREEDOM60 Syringe Infusion System. RMS believes this knock-off tubing, marketed as the same product, fails to meet RMS specifications. Furthermore, we believe that using such non-RMS tubing with the FREEDOM60 Syringe Infusion System could potentially result in **uncontrolled flows that could lead to patient injury or death.**
>
> While RMS investigates whether legal action against unauthorized sets is necessary to protect customers and patients, we urge you to use caution and refer to the product labeling including the FREEDOM60 Instructions for Use which includes the following precaution:
>
> Caution: Use only FREEDOM60 tubing sets manufactured by RMS Medical Products. Use of any other tubing may cause the syringe to eject from the pump and eventually cause internal damage to the pump. Use of any other flow rate control tubing set may cause over or under delivery or medication to the patient, which could result in injury or death.
>
> Please keep in mind that patient safety may be compromised by the use of unapproved and incompatible flow control tubing sets to deliver drugs. In addition, regulatory, patent infringement, reimbursement, and other issues may also arise. Moreover, use of non-RMS flow rate tubing voids the warranty for the FREEDOM60 Syringe Infusion Pump.
>
> Please note that the FREEDOM60 Calculator is designed and tested for use only with FREEDOM60 Syringe Infusion Pump connected to RMS FREEDOM60 Flow Rate Tubing. Using the calculator with non-RMS tubing may result in inaccurate flow rates.

70. Further, Sealfon and RMS's conduct was not limited to the United States. In or around 2015, Sealfon and RMS sent the following letter to customers in Denmark, Sweden, Norway, UK and perhaps further places:



RMS™
MEDICAL PRODUCTS

TO ALL CUSTOMERS OF THE FREEDOM60®

Here is important information for users/providers of the FREEDOM60®:

The RMS FREEDOM60® Syringe Infusion System was cleared as a medical device by the U.S. Food and Drug Administration (FDA) as a complete system which included the pump, syringe and tubing set. Each of the components is integral to the safe use of the pump. The use of the RMS FREEDOM60® Flow Rate Tubing, in particular, is required to maintain the consistent flow rates you expect to receive from the FREEDOM60® Syringe Infusion System.

We recently learned that attempts have been made to encourage users of the FREEDOM60® to use non-RMS flow rate tubing with the FREEDOM60® pump. This information causes us to be concerned because, to the best of our knowledge, such knock-off tubing has not been cleared by the FDA for use with the FREEDOM60® pump, nor tested in accordance with our stringent release criteria to confirm that it can be safely and effectively used in the RMS FREEDOM60® Syringe Infusion System. RMS believes that this knock-off tubing, marketed as the same product, fails to meet RMS specifications. Furthermore, we believe that using such non-RMS tubing with the FREEDOM60® Syringe Infusion System could potentially result in **uncontrolled flows that could lead to patient injury or death.**

While RMS investigates whether legal action against unauthorized sets is necessary to protect customers and patients, we urge you to use caution and refer to the product labeling including the *FREEDOM60® Instructions for Use* which includes the following precaution:

> Caution: Use only FREEDOM60® tubing sets manufactured by RMS Medical Products. Use of any other tubing set may cause the syringe to eject from the pump and eventually cause internal damage to the pump. Use of any other flow rate control tubing set may cause over or under delivery of medication to the patient, which could result in injury or death.

Please keep in mind that patient safety may be compromised by the use of unapproved and incompatible flow control tubing sets to deliver drugs. In addition, regulatory, patent infringement, reimbursement, and other issues may also arise. Moreover, use of non-RMS flow rate tubing voids the warranty for the FREEDOM60® Syringe Infusion Pump.

Please note that the FREEDOM60® Calculator is designed and tested for use only with FREEDOM60® Syringe Infusion Pump connected to RMS FREEDOM60® Flow Rate Tubing. Using the calculator with non-RMS tubing may result in inaccurate flow rates.

Should you have any questions or concerns, do not hesitate to contact us at 800-624-9600.

Sincerely,

Andy Sealfon

71. The regulatory agencies in the various countries delayed EMED's market entrance based upon the letter.

72. Immediately following the Safety Bulletin, RMS, through Sealfon, rebranded its own Infusion Extension Set as Precision Flow Rate Tubing Sets and disseminated information to the purchasing public and the Subject Self-administered SCIg Market that the Freedom60 was exclusively compatible with its own Precision Flow Rate Tubing Sets.

73. Sealfon personally presented an RMS copied version of EMED's VersaRate at the RMS booth at the ESID in Prague in 2014, Sealfon personally presented an RMS copied version

of EMED's VersaRate at the RMS booth at the ESID in Prague in 2014 (Infusets); needle sets (Soft Glide sets); and pump (SCIG60) has created misapprehension and distrust in the Subject Self-administered SCIg market about the quality of EMED's infusion products, including its EMED Infuset Rate Control Sets, Softglide needle sets, SCIg60 Pump, and the like, and have further interfered with or disrupted the economic relationships between EMED and its existing and potential customers resulting in irreparable harm to EMED.

74. RMS, through Sealfon, has promoted, and continues to promote its Rate Control Sets through dissemination of these statements and advertisements while disregarding the injunction in place. As a result of these actions, RMS has wrongfully diverted sales of SCIG family of sets away from EMED, namely from its EMED Infuset Rate Control Sets, Softglide needle sets, SCIg60 Pump.

3. RMS Commissioned and Submitted False and/or Misleading Reports to the FDA Alleging EMED was Marketing Dangerous Products

75. On information and belief, RMS opened up a channel of communication with the FDA through which RMS funneled false and/or misleading "independent reports," a number of which were generated by an individual who received previous donations from RMS.

76. On or about February 02, 2018, Marc Somelofski, RMS' then Regulatory Affairs Director, informed Paul Lambert of EMED by e-mail that Sealfon, RMS' CEO, hired Dr. Fred Ma of Medical Quality International, and a former FDA official, Larry Pilot, to draft a false and/or misleading consumer complaint which indicated to the FDA that EMED was marketing dangerous products.[5] This email also describes how, in an end-run around the injunction barring RMS from making further disparaging comments about EMED's products (including the Infuset and

[5] *See* Exhibit A, February 2, 2016 Somelofski e-mail.

VersaRate Rate Control Sets), and in order to keep communications off of RMS' server, Sealfon corresponded with Dr. Ma using a private email account.

77. As a result of these actions EMED has suffered actual damage in an amount equal to the lost market share attributable to the Sealfon's and RMS's actions complained of herein. After RMS's Safety bulletin published claiming EMED's rate sets (Infusets) may kill patients, the fast conversion of customers to EMED' Infusets stopped. In fact, several customers, including at least Curascript, Walgreens, Accredo, BioRx, and Coram canceled plans to convert to EMED Infusets. Further, RMS illegal marketing of the Freedom 60 as a system which was a) not FDA cleared for SCIg and b) not a system further damaged EMED in an amount equal to its lost system and accessory sales, including pump sales, rate set sales and needle set sales.

78. RMS has made and continues to make the same or similar false allegations regarding the efficacy and safety hazards of using EMED's Rate Control Sets with the Freedom 60 pump in direct and flagrant violation of the preliminary injunction obtained against it.

C. RMS Disparagement Campaign Targeted at EMED's Pump (SCIg60)

79. EMED pioneered the development of subcutaneous sets specifically designed to meet the unique needs of the Subject Self-administered SCIg market. In 2004, EMED completed a family of subcutaneous needle sets that quickly came to be the gold standard for use by patients with PIDD or PI. Originally, in the US home healthcare market, Accredo, Coram, Option Care, BioScript, Nufactor and others, adopted the EMED needle sets as part of their protocols and rolled out home therapies across the country.

80. Subsequent to, and during the rollout, several Infusion Pumps were used for this therapy based on specific pump types that home health care pharmacies had in the pump inventories. Electromechanical pumps dominate the international markets, but because Medicare

allowed exclusively for mechanical pumps, such Infusion Pumps became the established standard for the US market.

81. RMS's marketing strategy, through Sealfon, was focused on pushing the FREEDOM60 Infusion Pump for SCIg use regardless of whether it was cleared for such use.[6] Prior to clearance, for many years, its marketing campaign was designed to distribute the FREEDOM60 Infusion Pump for SCIg on a national scale. Due in large part due to Sealfon and RMS's illegal anticompetitive behavior, the FREEDOM60 became the market-dominant infusion pump in the Subject Self-administered SCIg Market. While not cleared by the FDA, RMS received a Warning Letter issued by the FDA criticizing such misleading and illegal marketing of the FREEDOM60 Infusion Pump. This Warning Letter stated in pertinent part:

> The FDA requests that your firm immediately cease activities that result in the misbranding or adulteration of the aforementioned FREEDOM60 and Freedom Edge Syringe Infusion Pumps and RMS HIgH-Flo Subcutaneous Safety Needle Sets, such as the commercial distribution of the devices for the uses discussed above.

82. Ignoring the FDA's Warning Letter, RMS continued to market the FREEDOM60 Infusion Pump as before, thereby misleading its customers to think that the Warning Letter was of no consequence. Such illegal marketing resulted in RMS gaining a dominant position in the U.S., where mechanical pumps are currently the only pumps for which consumers can receive reimbursement in the Subject Self-administered SCIg Market. Meanwhile, RMS continued to act and make statements affecting the Subject Self-administered SCIg Therapy Market for EMED:

> (1) We have become aware of a new mechanical pump entry on the market which we do not believe to have FDA approval. … The company offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60. We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60 Systems may be unsafe,

[6] *See* Exhibit B, letter from Sealfon to Neil Ross.

can create a health risk to the patient, including death, and would void the warranty of the pump.[7]

(2) There is a mechanical pump, manufactured by a competitor, which we do not believe to have FDA clearance. The new pump uses a prior design of a simple coil spring which does not create a constant pressure and which had been removed from the market several years ago.[8]

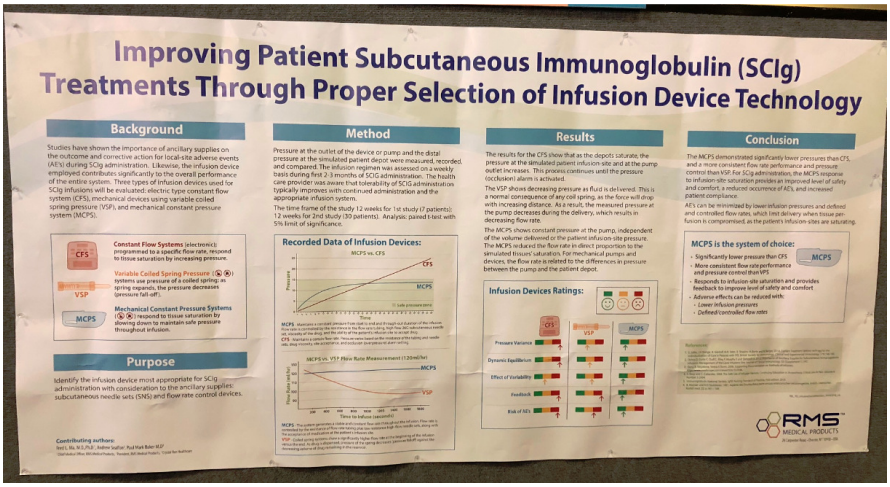
83. These statements are unfounded and designed to drive customers away from EMED's its EMED Rate Control Sets, Softglide needle sets, SCIg60 Pump, and the like and towards the FREEDOM60 Infusion Pump RMS Rate Control Sets.

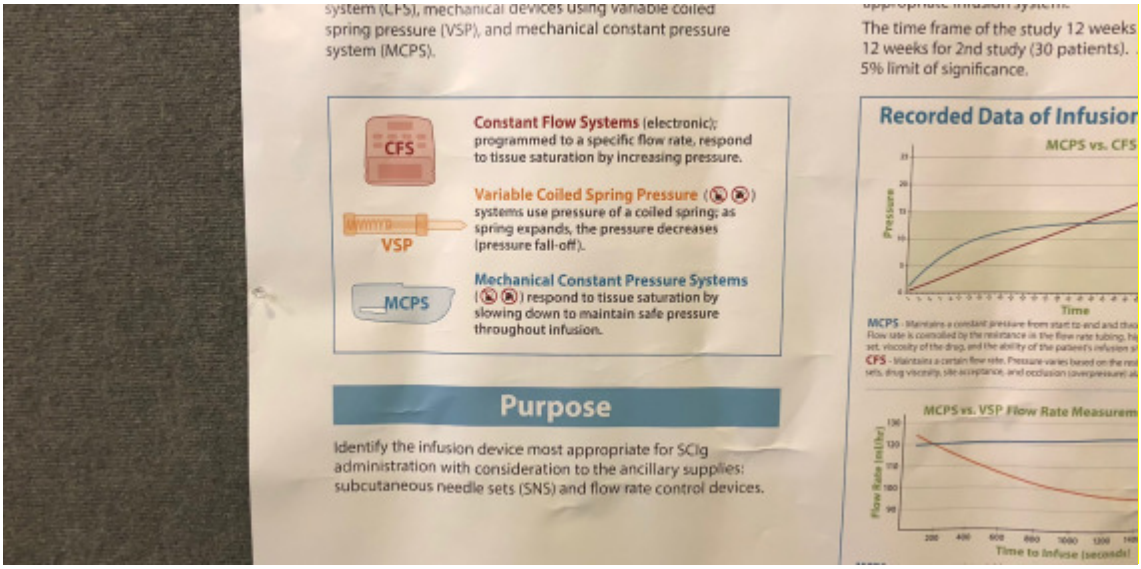
84. EMED worked with European, Canadian, and U.S. regulatory authorities to obtain market clearance for its SCIg specific Infusion Pump—the SCIg60. In December of 2016, the FDA issued the first clearance for a pump specifically for the administration of Ig.[9] The 510K included the SCIg60 Infusion Pump and Rate Control Sets necessary to control flow rate in mechanical infusion pumps. Despite EMED's clearance, Sealfon has been stating that the Freedom 60 outperforms the SCIg60 while marketing the Freedom 60 illegally for SCIg indications for many years. For example the Freedom 60 was specifically contraindicated to be used with blood products. In violation of FDA regulations, RMS modified the Freedom 60 label removing this contraindication to attempt to eliminate EMED's pump from the market.

85. RMS, and specifically Sealfon, continued to disparage EMED and its SCIg60 infusion pump. During a poster session at NHIA from April 23-26, 2018, which Sealfon personally heralded and presented a poster comparing the Freedom 60 with a mechanical and electronic pump. The charts in the poster are geared to misrepresent that the Freedom60 is the only pump that has adequate performance for the administration of SCIg. The poster shows that a variable coiled

[7] RMS: July 15, 2013 SEC Form 10-Q
[8] RMS stated in its July 15, 2014 SEC form 10-Q:
[9] 510K161906

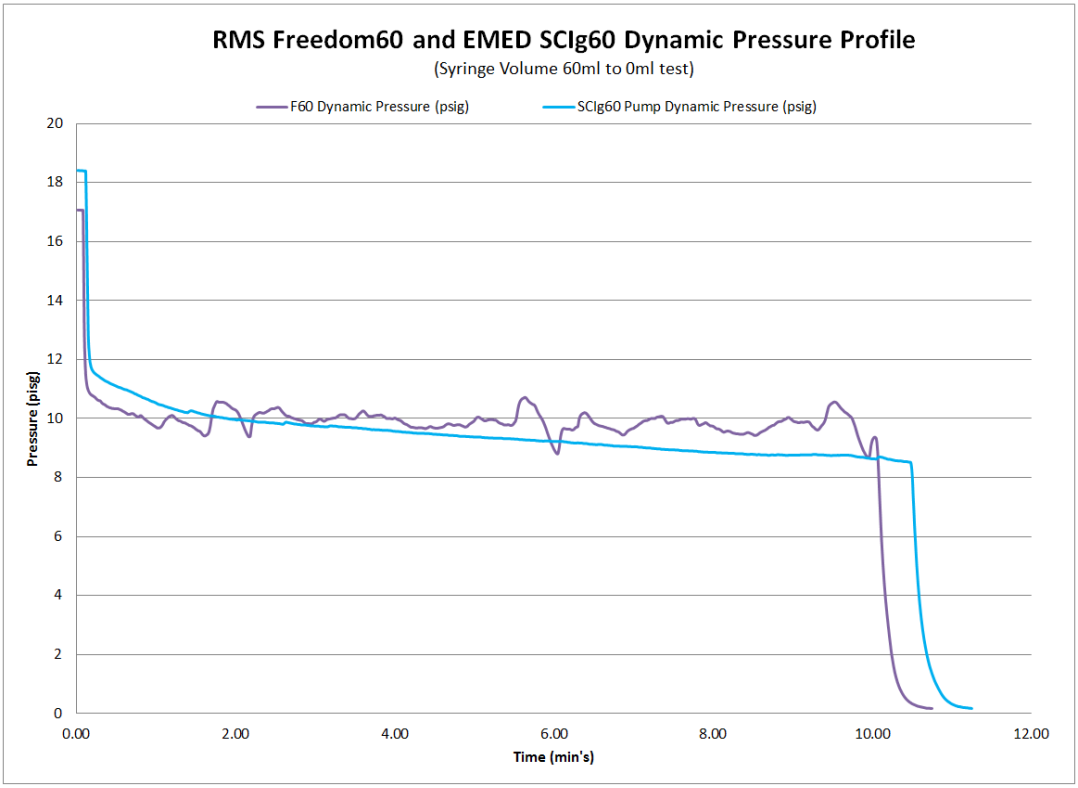
spring pump is inferior to the FREEDOM60 Infusion Pump. While RMS does not mention EMED by name, consumers in the market know the pump hat EMED markets.





86. Contrary to what the Sealfon poster purports, the comparative performance of the SCIG60 and Freedom 60 pumps is shown below. The chart is based on actual performance of both pumps during the delivery of 60 ml of fluid and it shows the dynamic pressure profile of both instruments. Sealfon's underlying objective is mischaracterizing the pump performance in the poster and other prior instances is to mislead the public and create a false and undue advantage for RMS to eliminate competition in the market.

EMED's EMPIRICAL TESTING OF THE SCIG60 AND THE FREEDOM 60 PUMPS



87. Sealfon's statements in the poster presentation are false and have caused damage to EMED at least through lost SCIg60 sales.

D. Sealfon's Former Associates Admit His Anticompetitive Behavior.

88. Sealfon statements concerning EMED included communication with RMS's executives. For example, Marc Somelofski, RMS' former Quality and Regulatory Manager at RMS contacted EMED and stated that Sealfon had established a poor image of EMED and its executives throughout the RMS organization. He stated: "Pretty bad things are said about EMED out there" referring to conversations at RMS's premises.

89. Likewise, Jeff Johnston, CEO of 800 Meters, a marketing firm that carried out PR campaigns for RMS told EMED during a phone conversation on January 31, 2018 that Sealfon represented to his board that RMS had 95% of the SCIG market, apparently in an attempt to show his marketing strategy was working. Additionally, Johnston stated that Sealfon was obsessed with EMED and that he was determined to get EMED out of the PI market, including the Subject Self-administered SCIg Market, and would do so in less than "two years."

VI. ANTITRUST INJURY TO CONSUMERS AND COMPETITORS

90. Through the unlawful acts and practices described herein RMS, due to the actions of Sealfon, has harmed competition, consumers and innovation by at least causing consumers to pay supracompetitive prices for Infusion systems, including pumps, rate sets and needle sets, in the Subject Self-administered SCIg Therapy Market. Those practices, described herein, have also allowed RMS to obtain and maintain dominant positions in the Products Market and Subject Self-administered SCIg Therapy Market.

91. The actions complained of here have tended to prevent consumers from using needle sets and Rate Control Sets other than RMS needle sets and Rate Control Sets when an RMS pump is used. Therefore, RMS has broadened the scope of the published patent application, and the likely patent grant, contained within the RMS Patents beyond that which is statutorily allowed, in an anticompetitive manner, the effect of which has been to increase prices, stifle innovation, and damage both the public (consumers) and RMS's competitors, including EMED.

92. The effect on the Subject Self-administered SCIg Therapy Market, in an anticompetitive manner, is to increase prices, stifle innovation, and damage both the public (consumers) and RMS's competitors, including EMED.

93. RMS's anticompetitive conduct, due to the actions of Sealfon, has deterred the development of competing products, damaging consumers by depriving them of a choice of products with different and possibly superior sets of features.

94. Through the unlawful acts and practices described herein Sealfon, has harmed competition, consumers and innovation by at least causing consumers to pay supracompetitive prices for pumps, rate sets and needle sets in the Subject Self-administered SCIg Therapy Market.

95. The actions of Sealfon constitute antitrust violations including at least knowingly fixing prices to the detriment of the consumer.

VII. EMED HAS STANDING AS AN ANTITRUST PLAINTIFF

96. Plaintiff re-alleges and incorporates by reference each of the allegations set forth above in paragraphs 1-95.

(a) EMED's injuries are of the type the antitrust laws were intended to prevent and flow from that which makes RMS's acts unlawful, i.e. there is a high degree of directness between the anticompetitive injuries suffered by EMED and violations of the title 15 USC §§1 and 2;

(b) RMS's conduct demonstrates an improper motive to dominate the Subject Self-administered SCIg Therapy Market;

(c) an impermissible extension of a patent grant are matters Congress redresses with the antitrust laws;

(d) appropriate damages to redress the anticompetitive actions of RMS are not speculative; and,

(e) the risk of duplicate recoveries is not great.

COUNT I:
TYING
(For Violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. §1)

Violations Resulting from Unlawful Tying and Conspiracy

97. Plaintiff re-alleges and incorporates by reference each of the allegations set forth in paragraphs 1-96.

98. RMS has substantial market power in the Subject Self-administered SCIg Therapy Market, due to the actions of Sealfon.

99. All of these markets are for goods and not services.

100. There is no appropriate or legitimate business justification for RMS's use of product warranties, trade shows, advertisements, training sessions that would counterbalance the clear anticompetitive effects of its tying conduct, including the foreclosure of competition in the Subject Self-administered SCIg Therapy Market.

101. There is no appropriate or legitimate business justification for RMS's use of product warranties, trade shows, advertisements, training sessions that would counterbalance the clear anticompetitive effects of its tying conduct, including the foreclosure of competition in the Subject Self-administered SCIg Therapy Market.

102. This unlawful conduct has harmed competition in that market and has caused injury to every buyer of an Infusion system in the Subject Self-administered SCIg Therapy Market. Prices in the Subject Self-administered SCIg Therapy Market for pumps, Rate Control Sets and needle sets are higher than they would have been in a competitive market; the supply and selection of products available is lower than it would be in a competitive market; and the number and effectiveness of competitors have been diminished by unlawful means.

103. The anticompetitive conduct described herein has damaged Plaintiff, as described in 15 U.S.C. §15, and is in violation of the Sherman Antitrust Act, 15 U.S.C. §1.

104. Plaintiff is entitled to a trebling of damages.

105. Plaintiff is entitled to a reasonable attorneys' fee and cost, which shall also be trebled.

COUNT II:
MONOPOLIZATION
(For Violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. §2)
Violations Resulting from the Unlawful Acquisition or Maintenance of Monopoly Power in the Subject Self-administered SCIg Therapy Market

106. Plaintiff re-alleges and incorporates by reference each of the allegations set forth above in paragraphs 1-105.

107. Through the actions described herein, RMS, due to the actions of Sealfon, has willfully acquired and maintained monopoly power in the Subject Self-administered SCIg Therapy Market. This conduct has harmed competition in that market and has caused injury to every buyer of pumps, rate sets and needles sets in the Subject Self-administered SCIg Therapy Market by at least removing competition, reducing innovation and raising prices. Prices in the Subject Self-administered SCIg Therapy Market are higher than they would be in a competitive market; the supply and selection of products available is lower than it would be in a competitive market; and the number and effectiveness of competitors have been diminished by RMS's unlawful means.

108. There is no appropriate or legitimate business justification for the actions and conduct which have facilitated RMS's monopolization of the Subject Self-administered SCIg Therapy Market.

109. The anticompetitive conduct described herein has damaged Plaintiff, as described in 15 U.S.C. §15, and is in violation of the Sherman Antitrust Act, 15 U.S.C. §2.

110. Plaintiff is entitled to a trebling of damages.

111. Plaintiff is entitled to a reasonable attorneys' fee and cost, which shall also be trebled.

COUNT III: ATTEMPTED MONOPOLIZATION
(For Violation of Section of the Sherman Antitrust Act, 15 U.S.C. §2)
Violations Resulting from Unlawful Attempted Monopolization of the Subject Self-administered SCIg Therapy Market

112. Plaintiff re-alleges and incorporates by reference each of the allegations set forth above in paragraphs 1-111.

113. RMS, due to the actions of Sealfon, RMS has acted with specific intent to monopolize the Subject Self-administered SCIg Therapy Market as is illustrated by its anticompetitive conduct including product warranties, trade shows, advertisements, training sessions against other Subject Self-administered SCIg Therapy Market consumers and manufacturers.

114. There was and is a dangerous possibility that RMS will succeed in its attempt to monopolize the Subject Self-administered SCIg Therapy Market because RMS controls a large percentage of that market and has the ability and actually does exclude its competitors through use of anticompetitive contract provisions in its advertising. Further success in excluding competitors from the Subject Self-administered SCIg Therapy Market will allow RMS to obtain an illegal monopoly over the Subject Self-administered SCIg Therapy Market.

115. This conduct has harmed competition in that market, making the supply and selection of products available lower than it would be in a competitive market. RMS's unlawful attempted monopolization has also reduced the number and effectiveness of competitors in the Subject Self-administered SCIg Therapy Market and forced consumers to pay higher prices in the Subject Self-administered SCIg Therapy Market than they would in a competitive market.

116. There is no appropriate or legitimate business justification for the actions and conduct which have facilitated RMS's attempted monopolization of the Subject Self-administered SCIg Therapy Market.

117. The anticompetitive conduct described herein, if not halted and abated, will damage Plaintiff, as described in 15 U.S.C. §15, and is in violation of the Sherman Antitrust Act, 15 U.S.C.§2.

118. Plaintiff is entitled to a trebling of damages.

119. Plaintiff is entitled to a reasonable attorneys' fee and cost, which shall also be trebled.

COUNT IV: BUSINESS DISPARAGEMENT/PRODUCT DISPARAGEMENT

120. Plaintiff re-alleges and incorporates by reference each of the allegations set forth above in paragraphs 1-119.

121. RMS and Sealfon published disparaging statements about EMED's SCIg Needle Sets, including:

a. the FDA indicates the Infusion System (Freedom60 and Freedom Edge) must be used only as a system with other RMS components;

b. the Infusion System (Freedom60 and Freedom Edge) components will not work and can harm people when components other than RMS components are use;

c. the warranty for the Infusion System (Freedom60 and Freedom Edge) only applies if use with other RMS components;

d. without data or testing, or comparing the wrong devices, RMS advertises that its needles have better flow rate characteristics than EMED's needles;

e. RMS removed EMED needles from its calculator;

f. RMS used false and misleading representations regarding injection site reactions caused by needles that the relevant consumers, including but not

limited to Coram, Accredo Specialty Pharmacy, BioRx, and BioScrip, would understand to be EMED's SCIg needle sets as compared to RMS's needle set;

g. RMS used false and misleading representations regarding penetration forces necessary to relevant consumers, including but not limited to Coram, Accredo Specialty Pharmacy, BioRx, and BioScrip;

h. RMS's allegations that EMED's needle sets were dull and caused coring to customers including at least:

i. VA Medical Center, Dallas, Johnny White -- Bonham, TX

ii. All Home Infusion Inc. -- Flint, TX

iii. CVS/Specialty #48604-CAREMARK LLC -- Flower Mound, TX

iv. Frisco Allergy & Asthma Center -- Frisco, TX

v. US Bioservices TX -- Frisco, TX

vi. Walgreens Specialty Pharmacy # 13625 -- Frisco, TX

vii. Logic Medical -- Frisco, TX

viii. US BIOSERVICES CORP – TX -- Frisco, TX

ix. Americare Infusion Center -- Lewisville, TX

x. CSL Behring -- McKinney, TX

xi. AirCare -- Plano, TX

xii. Texas Star Pharmacy -- Plano, TX

xiii. CarePoint Partners – Texarkana -- Texarkana, TX

xiv. Artex Medical -- Texarkana, TX

xv. NORTH HEIGHTS PHARMACY -- Wake Village, TX

xvi. And others;

i. RMS's video at www.youtube.com/watch?v=0cao1fghREI providing disparaging comments about EMED's flow rate from its needle sets; and,

j. Others.

122. The disparaging statements about EMED's SCIg Needle Sets are false. RMS published the disparaging statements with actual malice and without privilege. EMED has suffered special damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

123. RMS and Sealfon published disparaging statements about EMED's Infusets, including, but not limited to:

a. RMS began representing to customers that the EMED Extension sets (rate sets) lacked FDA clearance for the RMS Freedom60 pump and that EMED's sets could cause severe patient injury or death;

b. RMS has made multiple representations to customers that EMED's devices should not be used with the Freedom 60 pump. RMS published a "Safety Bulletin" which it circulated in multiple countries including US, Europe and Canada to falsely represent to customers that EMED's Rate Control Sets could cause severe patient injury or death and that they did not have FDA clearance.

c. RMS improperly conditioned the validity of its pump's warranty on the use of RMS-branded accessories;

d. RMS published a safety Bulletin alleging that EMED's Infusets were unsafe for use with Freedom60;

e. In or around 2015, Sealfon and RMS sent letters to customers in Denmark, Sweden, Norway, UK and perhaps further places alleging the use of EMED Infusets with RMS pumps could cause patient death; and,

f. And others.

124. The disparaging statements about EMED's Infusets were false. RMS published the disparaging statements with actual malice and without privilege. EMED has suffered special damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

125. RMS and Sealfon published disparaging statements about EMED's Infusion Pumps and Infusion Systems including but not limited to the following statements:

a. We have become aware of a new mechanical pump entry on the market which we do not believe to have FDA approval. … The company offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60. We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60 Systems may be unsafe, can create a health risk to the patient, including death, and would void the warranty of the pump.

b. There is a mechanical pump, manufactured by a competitor, which we do not believe to have FDA clearance. The new pump uses a prior design of a simple coil spring which does not create a constant pressure and which had been removed from the market several years ago.

c. RMS, and specifically Sealfon, disparaged EMED and its SCIg60 infusion pump during a poster session at NHIA from April 23-26, 2018, comparing the Freedom 60 with a mechanical and electronic pump.

126. The disparaging statements about EMED's Infusion Pumps and Infusion Systems were false. RMS published the disparaging statements with actual malice and without privilege. EMED has suffered special damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

127. EMED is entitled to recover actual damages in at least the amount of the special damages, in an amount equal to the loss of market share (loss of business) for each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems or alternatively the loss of sales for each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems.

128. EMED is entitled to recover its expenses in counteracting the numerous publications by RMS of the disparaging material concerning each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems.

129. EMED is entitled to recover pre-judgement interest, post-judgment interest and court costs.

COUNT V: DEFAMATION – LIBEL AND SLANDER

130. Plaintiff re-alleges and incorporates by reference each of the allegations set forth above in paragraphs 1-129.

131. RMS and Sealfon published through tweets, poster presentations, and on information and belief through product demonstrations, both spoken and written disparaging statements about EMED's SCIg Needle Sets including but not limited to:

132. RMS and Sealfon published disparaging statements about EMED's SCIg Needle Sets, including:

a. the FDA indicates the Infusion System (Freedom60 and Freedom Edge) must be used only as a system with other RMS components;

b. the Infusion System (Freedom60 and Freedom Edge) components will not work and can harm people when components other than RMS components are use;

c. the warranty for the Infusion System (Freedom60 and Freedom Edge) only applies if use with other RMS components;

d. without data or testing, RMS advertises that its needles have better flow rate characteristics than EMED's needles;

e. RMS removed EMED needles from its calculator;

f. RMS used false and misleading representations regarding injection site reactions caused by needles that the relevant consumers, including but not limited to Coram, Accredo Specialty Pharmacy, BioRx, and BioScrip, would understand to be EMED's SCIg needle sets as compared to RMS's needle set;

g. RMS used false and misleading representations regarding penetration forces necessary to relevant consumers, including but not limited to Coram, Accredo Specialty Pharmacy, BioRx, and BioScrip;

h. RMS's allegations that EMED's needle sets were dull and caused coring to customers including at least:

i. VA Medical Center, Dallas, Johnny White -- Bonham, TX

ii. All Home Infusion Inc. -- Flint, TX

iii. CVS/Specialty #48604-CAREMARK LLC -- Flower Mound, TX

iv. Frisco Allergy & Asthma Center -- Frisco, TX

v. US Bioservices TX -- Frisco, TX

vi. Walgreens Specialty Pharmacy # 13625 -- Frisco, TX

vii. Logic Medical -- Frisco, TX

viii. US BIOSERVICES CORP – TX -- Frisco, TX

ix. Americare Infusion Center -- Lewisville, TX

x. CSL Behring -- McKinney, TX

xi. AirCare -- Plano, TX

xii. Texas Star Pharmacy -- Plano, TX

xiii. CarePoint Partners – Texarkana -- Texarkana, TX

xiv. Artex Medical -- Texarkana, TX

xv. NORTH HEIGHTS PHARMACY -- Wake Village, TX

xvi. And others;

i. RMS's video at www.youtube.com/watch?v=0cao1fghREI providing disparaging comments about EMED's flow rate from its needle sets; and,

j. Others.

133. The disparaging statements about EMED's SCIg Needle Sets were defamatory and false. RMS published the disparaging statements with actual malice or negligence. Further, the defamation is of such a character that RMS is strictly liable. EMED has suffered damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

134. RMS and Sealfon published through tweets, poster presentations, and on information and belief through product demonstrations, both spoken and written disparaging statements about EMED's Infusets including but not limited to:

a. RMS began representing to customers that the EMED Extension sets (rate sets) lacked FDA clearance for the RMS Freedom60 pump and that EMED's sets could cause severe patient injury or death;

b. RMS has made multiple representations to customers that EMED's devices should not be used with the Freedom 60 pump. RMS published a "Safety Bulletin" which it circulated in multiple countries including US, Europe and Canada to falsely represent to customers that EMED's Rate Control Sets could cause severe patient injury or death and that they did not have FDA clearance.

c. RMS improperly conditioned the validity of its pump's warranty on the use of RMS-branded accessories;

d. RMS published a safety Bulletin alleging that EMED's Infusets were unsafe for use with Freedom60;

e. In or around 2015, Sealfon and RMS sent letters to customers in Denmark, Sweden, Norway, UK and perhaps further places alleging the use of EMED Infusets with RMS pumps could cause patient death; and,

f. And others.

135. The disparaging statements about EMED's Infusets were defamatory and false. RMS published the disparaging statements with actual malice or negligence. Further, the defamation is of such a character that RMS is strictly liable. EMED has suffered damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

136. RMS and Sealfon published through tweets, poster presentations, and on information and belief through product demonstrations, both spoken and written disparaging statements about EMED's Infusion Pumps and Infusion Systems including but not limited to:

a. We have become aware of a new mechanical pump entry on the market which we do not believe to have FDA approval. … The company offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60. We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60 Systems may be unsafe, can create a health risk to the patient, including death, and would void the warranty of the pump.

b. There is a mechanical pump, manufactured by a competitor, which we do not believe to have FDA clearance. The new pump uses a prior design of a simple coil spring which does not create a constant pressure and which had been removed from the market several years ago.

c. RMS, and specifically Sealfon, disparaged EMED and its SCIg60 infusion pump during a poster session at NHIA from April 23-26, 2018, comparing the Freedom 60 with a mechanical and electronic pump.

137. The disparaging statements about EMED's Infusion Pumps and Infusion Systems were defamatory and false. RMS published the disparaging statements with actual malice or negligence. Further, the defamation is of such a character that RMS is strictly liable. EMED has suffered special damages in the form of pecuniary loss and loss of market share that has been realized as herein described.

138. EMED is entitled to recover actual damages in at least the amount of the special damages, in an amount equal to the loss of market share (loss of business) for each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems or alternatively the loss of sales for each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems.

139. EMED is entitled to recover its expenses in counteracting the numerous publications by RMS of the disparaging material concerning each of the SCIg Needle Sets, Infusets, Infusion Pumps, and SCIg Infusion Systems.

140. EMED is entitled to recover pre-judgement interest, post-judgment interest and court costs.

VIII. PRAYER FOR RELIEF

1. WHEREFORE, EMED prays for relief as follows:

a. enter judgment that Defendant RMS is in violation of Section 1 of the Sherman Antitrust Act, awarding Plaintiff its actual damages, its attorneys' fees, its court costs, pre- and post-judgment interest, a trebling of the actual damages attorneys' fees, curt costs and interest;

b. enter judgment that Defendant RMS is in violation of Section 2 of the Sherman Antitrust Act, awarding Plaintiff its actual damages, its attorneys' fees, its court costs, pre- and post-judgment interest, a trebling of the actual damages attorneys' fees, court costs and interest;

c. enter judgment that Defendant is in violation of Section 2 of the Sherman Antitrust Act resulting from Defendant RMS's attempted monopolization, awarding Plaintiff its actual damages, its attorneys' fees, its court costs, pre- and post-judgment interest, a trebling of the actual damages attorneys' fees, court costs and interest;

d. enter judgment that each of Defendants RMS and Sealfon have disparaged EMED's business and products, awarding Plaintiff its actual damages, its attorneys' fees, its court costs, pre- and post-judgment interest, and enhancing the actual damages at least by a factor of three;

e. enter judgment that each of Defendants RMS and Sealfon have defamed EMED, awarding Plaintiff its actual damages, its attorneys' fees, its court costs, pre- and post-judgment interest, and enhancing the actual damages at least by a factor of three; and,

f. award Plaintiff such other and further relief as this Court deems just and proper.

Respectfully submitted,

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Counsel for Plaintiff
EMED Technologies Corporation

CERTIFICATE OF SERVICE

Pursuant to the Federal Rules of Civil Procedure and Local Rule CV-5, I hereby certify that all counsel of record who have appeared in this case are being served today, May 9, 2018, with a copy of the foregoing via electronic mail to JSawtelle@shermanhoward.com.

/s/ William P. Ramey, III
William P. Ramey, III